

Inventor : Ignatious
Serial No. : 09/744,350
Filed : May 22, 2001
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COMPLETE LISTING OF ALL CLAIMS, WITH MARKINGS AND STATUS IDENTIFIERS
(Currently amended claims showing deletions by ~~striking through~~ and additions by underlining)

1 - 16 (canceled)

17 (original): A process for preparing polymer microspheres and nanospheres comprising a polymer and a peptide, which comprises the steps of:

dissolving a salt of a peptide complexed with an anionically or cationically functionalized biodegradable polyester in an organic solvent to form a solution;

dispersing the solution in an aqueous solution of a surfactant; and

evaporating the organic solvent to isolate the polymer microspheres and nanospheres.

18 (currently amended): A process according to claim 17, wherein the salt of a peptide is complexed with ~~a anionically functionalized biodegradable polyester is~~ functionalized with an anionic moiety selected from the group consisting of carboxylate, phosphate and sulfate ~~and the cationically functionalized biodegradable polyester is~~ functionalized with a cationic moiety selected from the ~~group consisting of amino, amidino, guadino, ammonium, cyclic amino groups and nucleic acid bases.~~

19 (original): A process according to claim 18 wherein the organic solvent is dichloromethane, chloroform or ethyl acetate.

20 (previously presented): A process according to claim 19, wherein the organic solvent is dichloromethane

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and the concentration of the polyester in the dichloromethane is 0.5% to 30% by weight.

21 (previously presented): A process according to claim 20, wherein the concentration of the polyester in the dichloromethane is 0.5% to 10% by weight.

22 (original): A process according to claim 21, wherein the surfactant is one or more of sodium oleate, sodium stearate, sodium laurylsulphate, a poly(oxyethylene) sorbitan fatty acid ester, polyvinylpyrrolidone, polyvinyl alcohol, carboxymethyl cellulose, lecithin, gelatin or hyaluronic acid.

23 (withdrawn): A process according to claim 22, wherein the surfactant is polyvinyl alcohol and the pH of polyvinyl alcohol is 6.5-7.5.

24 (withdrawn): A process according to claim 23, wherein the pH of polyvinyl alcohol is 6.9-7.1.

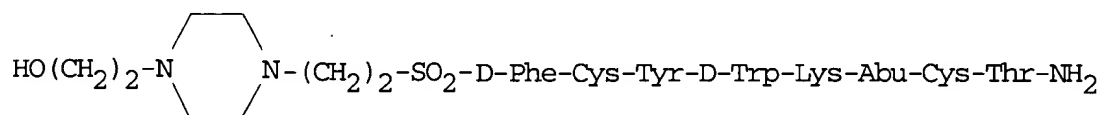
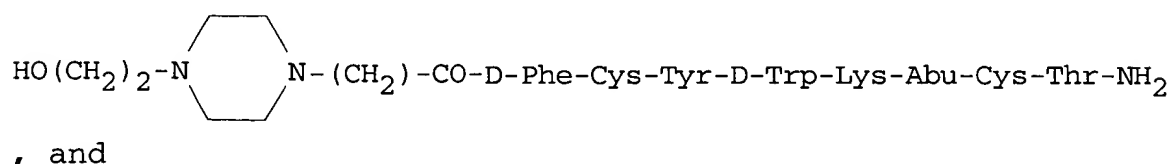
25 (previously presented): A process according to claim 22, wherein the peptide is growth hormone releasing peptide, luteinizing hormone-releasing hormone, somatostatin, bombesin, gastrin releasing peptide, calcitonin, bradykinin, galanin, melanocyte stimulating hormone, growth hormone releasing factor, amylin, tachykinins, secretin, parathyroid hormone, enkephalin, endothelin, calcitonin gene releasing peptide, neuromedins, parathyroid hormone related protein, glucagon, neurotensin, adrenocorticotrophic hormone, peptide YY, glucagon releasing peptide, vasoactive

intestinal peptide, pituitary adenylate cyclase activating peptide, motilin, substance P, neuropeptide Y or TSH, or an analogue or a fragment thereof, or a pharmaceutically acceptable salt thereof.

26 (withdrawn): A process according to claim 25, wherein the peptide is the LHRH analogue of the formula pyroGlu-His-Trp-Ser-Tyr-D-Trp-Leu-Arg-Pro-Gly-NH₂.

27 (withdrawn): A process according to claim 26, wherein the polymer is polylactide-co-glycolide, polycaprolactone or polyanhydride or a copolymer or blends thereof.

28 (original): A process according to claim 25, wherein the peptide is selected from the group of somatostatin analogues consisting of H-D-β-Nal-Cys-Tyr-D-Trp-Lys-Thr-Cys-Thr-NH₂,



29 (previously presented): A process according to claim 28, wherein the polyester is polylactide-co-glycolide, polycaprolactone or polyanhydride or a copolyester or blends thereof.

30 (withdrawn): A polymer microsphere made according to the process of claim 17.

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31 (withdrawn): A polymer microsphere made according to the process of claim 27.

32 (withdrawn): A polymer microsphere made according to the process of claim 29.

33 - 48 (canceled)

49 (new): A process according to claim 17, wherein the salt of a peptide is complexed with a biodegradable polyester functionalized with a cationic moiety selected from the group consisting of amino, amidino, guanidino, ammonium, cyclic amino groups and nucleic acid bases.

50 (new): A process according to claim 49 wherein the organic solvent is dichloromethane, chloroform or ethyl acetate.

51 (new): A process according to claim 50, wherein the organic solvent is dichloromethane and the concentration of the polyester in the dichloromethane is 0.5% to 30% by weight.

52 (new): A process according to claim 51, wherein the concentration of the polyester in the dichloromethane is 0.5% to 10% by weight.

53 (new): A process according to claim 52, wherein the surfactant is one or more of sodium oleate, sodium stearate, sodium laurylsulphate, a poly(oxyethylene) sorbitan fatty acid ester, polyvinylpyrrolidone, polyvinyl alcohol, carboxymethyl cellulose, lecithin, gelatin or hyaluronic acid.

54 (new): A process according to claim 53, wherein the surfactant is polyvinyl alcohol and the pH of polyvinyl alcohol is 6.5-7.5.

55 (new): A process according to claim 54, wherein the pH of polyvinyl alcohol is 6.9-7.1.

56 (new): A process according to claim 53, wherein the peptide is growth hormone releasing peptide, luteinizing hormone-releasing hormone, somatostatin, bombesin, gastrin releasing peptide, calcitonin, bradykinin, galanin, melanocyte stimulating hormone, growth hormone releasing factor, amylin, tachykinins, secretin, parathyroid hormone, enkephalin, endothelin, calcitonin gene releasing peptide, neuromedins, parathyroid hormone related protein, glucagon, neurotensin, adrenocorticotrophic hormone, peptide YY, glucagon releasing peptide, vasoactive intestinal peptide, pituitary adenylate cyclase activating peptide, motilin, substance P, neuropeptide Y or TSH, or an analogue or a fragment thereof, or a pharmaceutically acceptable salt thereof.

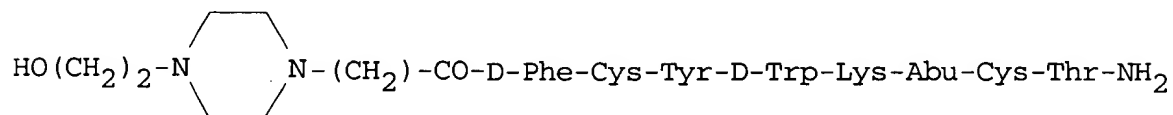
57 (new): A process according to claim 56, wherein the peptide is the LHRH analogue of the formula pyroGlu-His-Trp-Ser-Tyr-D-Trp-Leu-Arg-Pro-Gly-NH₂.

58 (new): A process according to claim 57, wherein the polymer is polylactide-co-glycolide, polycaprolactone or polyanhydride or a copolymer or blends thereof.

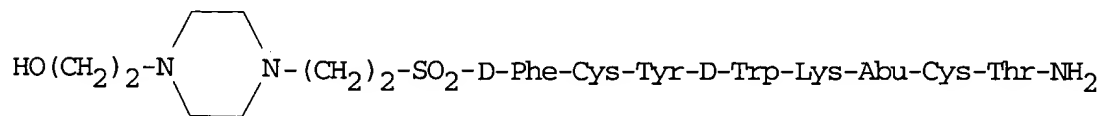
59 (new): A process according to claim 56, wherein

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the peptide is selected from the group of somatostatin analogues consisting of H-D- β -Nal-Cys-Tyr-D-Trp-Lys-Thr-Cys-Thr-NH₂,



, and



60 (new): A process according to claim 59, wherein the polyester is polylactide-co-glycolide, polycaprolactone or polyanhydride or a copolyester or blends thereof.

61 (new): A polymer microsphere made according to the process of claim 58.

62 (new): A polymer microsphere made according to the process of claim 60.